

Remarks

A. Objection to Specification

Objection is made to the specification as failing to provide disclosure of a thru lumen tubing forming a single lumen. Applicants direct the examiner's attention to Figs. 3, 4 and 5 together with the written description in paragraphs [0020], [0029], [0030] and [0032] of Pub. No. 2005/0054976. As shown and described, outer layer 150 forms a single shaft lumen 151 [0020].

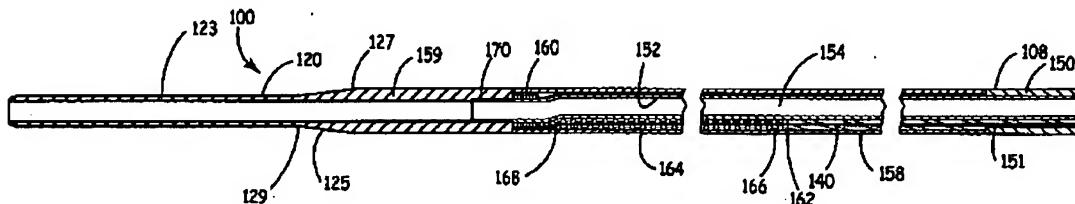


FIG. 3

The lumen 151 is further shown in cross section in Fig. 4, which is taken within a proximal portion of the shaft 106 (Fig. 1).

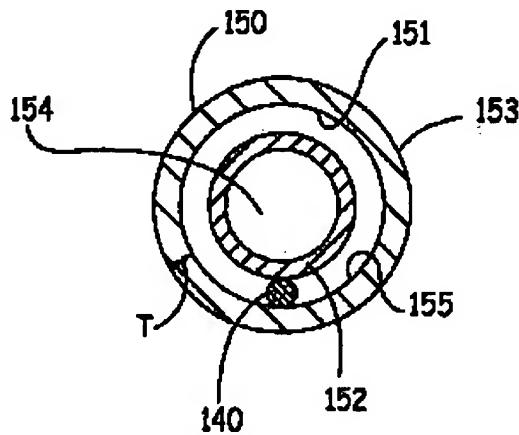


FIG. 4

Fig. 4 also illustrates the thru lumen tubing 152 [0029].

Fig. 5 illustrates a cross section of the shaft taken within a distal portion [0030].

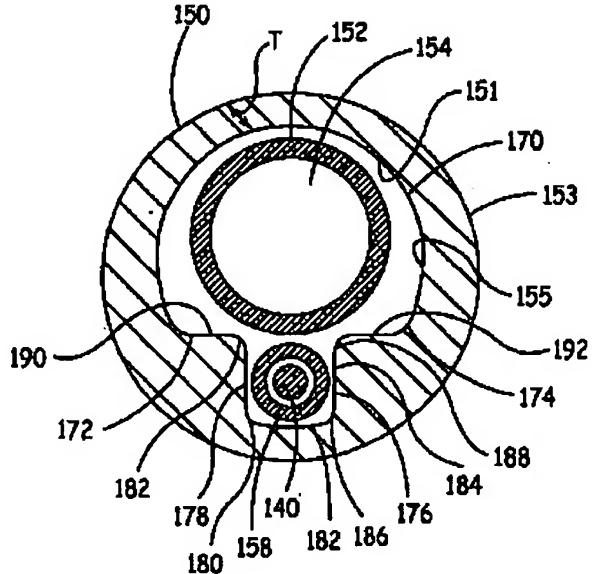


FIG. 5

As described in paragraph [0032], lumen 151 has a first lumen portion 170 and a second lumen portion 176, which includes a first side wall 178, a second side wall 184 and a bottom wall 182. The manipulator wire 140 is positioned within the second lumen portion 176.

There being disclosure of the claimed subject matter, the objection to the specification should be withdrawn.

Objection is further made to the term anchoring "device." The examiner contends that there is no disclosure in the specification of an anchoring "device." Rather, there is only disclosure of an anchoring "band." Applicants invite the examiner's attention to claim 21 as originally filed. Claim 21 includes the term anchoring "device." Claims as originally filed, by statute, constitute part of the specification. Accordingly, the specification discloses both an anchoring device and an anchoring band. The objection should be withdrawn.

B. Claim Rejections

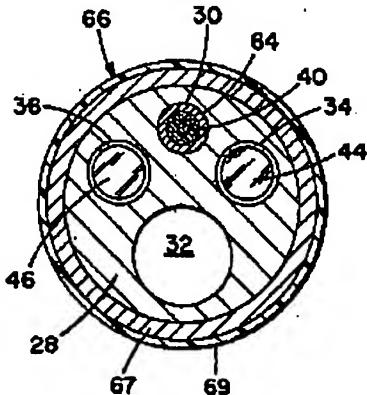
Claims 1, 6-12, 16, 19, 20, 22, and 41 are rejected as being obvious from Wardle (US 4,748,969) in view of Truckai (US 5,397,304). Wardle is relied upon as disclosing a deflectable tip medical therapy delivery device. The structure of Wardle, however, is mischaracterized. First, Wardle is actually a flexible shaft endoscope; Wardle is not a therapy delivery device. Second, according to paragraph 4 of the final office action, Wardle is characterized as:

1. an outer layer forms a single shaft lumen having a first lumen portion 28 positioned about the thru lumen tubing 32,
2. a manipulator wire 40 extends through lumen tubing 32,
3. a second lumen portion above 28 having a first side wall, a second side wall, and a bottom side wall, and
4. the second lumen portion is offset from and in fluid communication with the first lumen portion.

As shown in the drawing figures of Wardle, these characterizations of Wardle are incorrect.

Wardle shows the following in Fig. 2, which is a cross section of shaft 8 of the instrument:

FIG. 2



The structure shown is a shaft having a solid core 28 of a flexible material (col. 4, lines 57-60) within a cover 66 made of a wire braid sheath 67 and a polymer coating 69 (col. 5, lines 61-64). The core 28 has four passageways identified as: deflection conduit 30, working conduit 32, and two fiber optic conduits 34, 36.

Accordingly, contrary to the characterization in the office action, item 28 is not a lumen at all. A lumen is an open space, whereas item 28 is the solid core material within the cover 66 of the flexible shaft 8.

Also contrary to the characterization in the office action, deflection member 40 does not extend through conduit 32.

Moreover, the conduit 32 is described as providing a passageway through the length of the shaft. Conduit 32 provides the only "thru lumen" within the shaft 8. Conduits 30 and 32 are not first and second portions of a common lumen that are in fluid communication with one another.

Yet further, nowhere does Wardle exhibit that the deflection conduit 30 and deflection channel 56 for the deflection member 40 have a first side wall, a second side wall, and a bottom side wall.

Finally, to be noted as well is that, absent from the contentions in the final office action is any identification whatsoever as to what structure in Wardle constitutes the limitation of a "thru lumen tubing forming a thru lumen." As stated above, the only thru lumen in Wardle is conduit 32. But, conduit 32 is not formed by a thru lumen "tubing" at all much less one that resides within a shaft lumen.

Thus, contrary to the contention made in the final office action that Wardle "discloses the invention substantially as claimed," the structure disclosed in Wardle is nothing at all like the structure set forth in the claims.

The fundamental dispute concerning the grounds of rejection is that the coating 66 (the alleged "outer layer") of Wardle does not form a single shaft lumen. As stated above, the plain, ordinary meaning of "lumen" is that it is a *hollow space* within the bore of a tube such as a needle or catheter. The core 28, being a solid material wrapped by the coating and braid, therefore, is not a hollow

space and cannot be a lumen. The solid core 28 carries a plurality of conduits, each of which has a lumen (hollow space), thereby providing a plurality of lumens. When the term "lumen" is given its plain and ordinary meaning, as would be understood by a person of ordinary skill in the art, even as to its broadest reasonable interpretation, the structure disclosed in Wardle does not include and cannot reasonably be characterized as including the following:

"wherein the outer layer forms a single shaft lumen having a first lumen portion positioned about the thru lumen tubing and a second lumen portion, offset from and in fluid communication with the first lumen portion."

The obviousness rejection applies Wardle as essentially an anticipation of the independent claims. Truckai appears to be relied upon only for its disclosure of certain materials and durometer parameters, which are limitations of the dependent claims. Nowhere is there a contention that Truckai provides any of the structural limitations of the independent claims. Similarly, none of the other cited references (Hayzelden, Hobbs, Kousai, or Ponzi) provides any of the structural limitations of the independent claims. Accordingly, each rejection based on any combination of the cited references is without merit and should be withdrawn.

With this response, an earnest effort has been made to respond to all issues raised in the Final Office Action. In view of the above remarks, it is submitted that the claims are patentable and the application is in condition for allowance. Applicants request issuance of a notice of allowance.

Respectfully submitted,

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Date

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